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Amendment
Attorney Docket No. S63.2R-9493-US02

Remarks

This Amendment is in response to the Office Action dated **March 17, 2004**. Claims 1 – 15 are pending in this application. The Examiner withdrew his restriction requirement as to claims 4, 5, 7 and 8. The Examiner objected to claim 5 in paragraph 2 of the official action. The Examiner rejected claim 6 under §112 in paragraphs 3-5 of the action. The Examiner objected to the drawings in paragraph 6 of the action. The Examiner rejected claims 1-3 and 5-15 under §103 over Shull US 6143022 in view of Savin US 4950227. Claim 4 was rejected under §103 over Herweck in view of Savin.

In response, applicant has amended claim 5 to overcome the objection of paragraph 2 of the action and cancelled claim 6 to overcome the rejections of paragraphs 3-5 and the drawing objection of paragraph 6 of the action.

Applicants respectfully traverse the §103 rejections of paragraphs 7-10 of the action.

§103 Rejections

The Examiner has admitted that Shull does not disclose or teach a stent mounted on a balloon catheter having sleeves, and looks to Savin for its disclosure of a balloon catheter with a stent mounted thereto and having sleeves for securing and maintaining a reduced diameter of a self-expanding stent on the balloon.

Nor does Shull disclose a membrane which covers at least a portion of the stent to prevent flaring. The graft 20 of Shull has a completely different purpose than the problem being solved by the present invention. Shull discloses at Col. 1 line 60-65 that (emphasis added):

Attempts to address these problems include providing a suitable surface within the lumen for more controlled healing to occur in addition to the support provided by a stent. These attempts include providing a lining or covering in conjunction with an implanted stent. A stent with such a lining or covering is known in the art as a stent-graft.

Therefore, it can be seen that Shull does not disclose or teach using a lining or covering to prevent flaring, as in the present invention.

As 35 U.S.C. §103 and the Federal Circuit make clear, when considering obviousness, the Court must consider the claimed invention "as a whole". See *Ruiz v. A.B.*

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Chance Co., 69 USPQ2d 1686, 357 F3d 1270 (Fed. Cir. 2004) in which the Federal Circuit stated (emphasis added):

Section 103 of title 35 of the United States Code states:

A patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. 35 U.S.C. §103(a) (2000).

In making the assessment of differences, section 103 specifically requires consideration of the claimed invention "as a whole." Inventions typically are new combinations of existing principles or features. *Env'tl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698 [218 USPQ 865] (Fed. Cir. 1983) (noting that "virtually all [inventions] are combinations of old elements."). The "as a whole" instruction in title 35 prevents evaluation of the invention part by part. Without this important requirement, an obviousness assessment might break an invention into its component parts (A + B + C), then find a prior art reference containing A, another containing B, and another containing C, and on that basis alone declare the invention obvious. This form of hindsight reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new result – often the very definition of invention.

Section 103 precludes this hindsight discounting of the value of new combinations by requiring assessment of the invention as a whole. This court has provided further assurance of an "as a whole" assessment of the invention under §103 by requiring a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would select the various elements from the prior art and combine them in the claimed manner. In other words, the examiner or court must show some suggestion or motivation, before the invention itself, to make the new combination. See *In re Rouffet*, 149 F.3d 1350, 1355-56 [47 USPQ2d 1453] (Fed. Cir. 1998).

The Federal Circuit also discussed hindsight as follows:

("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."). *In re Lee*, 61 USPQ2d 1430 (Fed. Cir. 2002).

In order to combat impermissible hindsight, the Federal Circuit has also made it clear that the showing of a **motivation** to combine two or more references must be "**clear and particular**". See for example *Winner International Royalty Corp. v. Wang*, 53 USPQ2d 1580, 202 F3d 1340 (Fed. Cir. 2000), where the Federal Circuit stated (emphasis added):

When an obviousness determination is based on multiple prior art references, there must be a showing of some "teaching, suggestion, or reason" to combine the references. [Citation omitted].

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Although a reference need not expressly teach that the disclosure contained therein should be combined with another, [citation omitted] the showing of combinability, in whatever form, must nevertheless be "clear and particular."

As the Federal Circuit also stated:

"The factual inquiry whether to combine references must be **thorough and searching**." *Id.* It must be based on **objective evidence of record**. This precedent has been reinforced in myriad decisions, and cannot be dispensed with. (Emphasis added). In *re Lee*, 61 USPQ2d 1430 (Fed. Cir. 2002).

Applicant respectfully submits that the Examiner has not met the burden of showing a "clear and particular" motivation to combine Shull and Savin. One of ordinary skill in the art would have no reason, other than impermissible hindsight, to combine the teachings of Shull and Savin. Shull is totally and completely silent on using sleeves to hold the stent in place during deployment and Savin is completely silent on using a membrane to cover the stent to prevent flaring. Only by looking at the prior art through the lens of the present invention, by using impermissible hindsight, can the Examiner combine these two references. There is no objective evidence of record which would motivate or suggest to one of ordinary skill in the art to combine Shull and Savin.

Similarly, the rejection to claim 4 lacks any "clear and particular" showing of motivation to combine Herweck and Savin.

Therefore, applicant respectfully requests the §103 rejections to claims 1-5 and 7-15 be withdrawn. Based on at least the foregoing amendments and remarks, Applicants respectfully submit this application is in condition for allowance. Favorable consideration and prompt allowance of claims 1-5 and 7-15 are earnestly solicited.

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Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

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Date: June 17, 2004

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